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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,333	02/13/2002	Kevin P. Baker	PF514P1	4576

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HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER
O HARA, EILEEN B

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	10/073,333	BAKER ET AL.	
	Examin r	Art Unit	
	Eileen O'Hara	1646	

-- The MAILING DATE of this c mmunication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-19 and 27, in so far as they are drawn to polynucleotides of TR16, vectors, host cells and a method for producing a polypeptide recombinantly, classified in class 536, subclass 23.5, class 435, subclasses 320.1, 252.3 and 69.1, for example.

II. Claims 20, 26 and 28, drawn to TR16 polypeptides, classified in class 530, subclass 350.

III. Claims 21 and 25, in so far as they are drawn to antibodies to TR16, classified in class 530, subclass 388.22, for example.

IV. Claim 22, in so far as it is drawn to a method of treatment by administration of TR16 polypeptide, classified in class 514, subclass 2.

V. Claim 22, in so far as it is drawn to a method of treatment by administration of an agonist of TR16 protein, classified in class 514, subclass 2.

VI. Claims 23 and 24, drawn to a method of treatment by administration of an antagonist of TR16 protein, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

polynucleotides and polypeptides are physically and functionally distinct chemical entities that have different structures, activities and functions.

Inventions II and III are unrelated. In the instant case the polypeptides and antibodies are physically and functionally distinct chemical entities that have different structures, activities and functions.

Inventions I and each of inventions III, IV, V and VI are unrelated. The polynucleotides and antibodies are physically and functionally distinct chemical entities that have different structures, activities and functions, and the methods of inventions IV, V and VI do not use the polynucleotides of invention I.

Invention II is related to invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in the method of treatment of invention IV, but the polypeptides can also be used in a method of making antibodies, which is a materially different method.

Invention II is unrelated to each of inventions V and VI. The polypeptides are not used in the method of treatment with agonists and antagonists.

Inventions III and IV are unrelated. The antibodies of invention III are not used in the method of treatment with the polypeptide of invention II.

Invention III is related to each of inventions V and VI as product and process of use. In the instant case the antibodies can be used in the methods of treatment as agonists or

antagonists of the polypeptides, but the antibodies can also be used in a method of purifying the polypeptides, which is a materially different method.

Inventions IV, V and VI are each unrelated to the other. Though all of the inventions are methods of treatment, the compounds that are administered (polypeptide, agonist or an antagonist) are completely different from each other, and have different structures, functions and therapeutic effects, and thus are patentably distinct.

Further Restriction Within Group I

3. Applicants' claims are drawn to numerous patentably distinct nucleic acid TR16 sequences. If group I is elected, further restriction *within* the group is required, as follows:

The claims are drawn to numerous patentably distinct nucleic acids, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a nucleic acid, selected from the group consisting of:(i.e. elect one from the following Markush group): a nucleic acid comprising a polynucleotide encoding a TR16 protein (SEQ ID NOS: 2 and 4), **or** a nucleic acid comprising a polynucleotide encoding **one** of the epitope-bearing portions of a TR 16 receptor recited in claim 10 which are amino acids 51-67, 72-79, 94-104, 159-171, 180-185, 222-223, 238-242, 313-319, 325-346, 355-362, 385-395, 416-430, 456-465, 479-483, 530-535, 543-548, 569-579, 608-613, 627-639, 658-665, 702-707, 719-723, 749-747, 763-767, 837-842, 849-856, 886-893 and 950-955.

Further Restriction Within Group II

4. Applicants' claims are drawn to numerous patentably distinct TR16 polypeptide sequences. If group II is elected, further restriction *within* the group is required, as follows: The claims are drawn to numerous patentably distinct polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of a polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group): a polypeptide having an amino acid sequence selected from the group consisting of a TR16 protein (SEQ ID NOS: 2 and 4), **or** a nucleic acid comprising a polynucleotide encoding **one** of the epitope-bearing portions of a TR 16 receptor recited in claim 26 which are amino acids 51-67, 72-79, 94-104, 159-171, 180-185, 222-223, 238-242, 313-319, 325-346, 355-362, 385-395, 416-430, 456-465, 479-483, 530-535, 543-548, 569-579, 608-613, 627-639, 658-665, 702-707, 719-723, 749-747, 763-767, 837-842, 849-856, 886-893 and 950-955.

Further Restriction Within Group III

5. Applicants' claims are drawn to numerous patentably distinct antibodies to regions of TR16 polypeptide sequences. If group III is elected, further restriction *within* the group is required, as follows: The claims are drawn to numerous patentably distinct antibodies to specific polypeptide sequences, each of which constitutes a patentably distinct product. Applicant is required to elect a single invention of an antibody to a single polypeptide, selected from the group consisting of: (i.e. elect one from the following Markush group): an antibody to a polypeptide having an amino acid sequence selected from the group consisting of a TR16 protein (SEQ ID NOS: 2 and 4), **or** a nucleic acid comprising a polynucleotide encoding **one** of the

epitope-bearing portions of a TR 16 receptor recited in claim 26 which are amino acids 51-67, 72-79, 94-104, 159-171, 180-185, 222-223, 238-242, 313-319, 325-346, 355-362, 385-395, 416-430, 456-465, 479-483, 530-535, 543-548, 569-579, 608-613, 627-639, 658-665, 702-707, 719-723, 749-747, 763-767, 837-842, 849-856, 886-893 and 950-955.

Applicant is advised that this is not a species election.

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.1 or 530/350, each represents a patentably distinct product with distinct physical and functional characteristics. Further, the search for more than one product would be burdensome, because, in the case of the nucleic acid sequences, many are claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO: 1 as well as a 'reverse translation' search of the corresponding region of SEQ ID NO: 2, such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid or polypeptide, which requires a separate "word search" of the nucleic acid and protein databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids 1-963 of SEQ ID NO: 2 would reveal art pertaining to, for instance a nucleic acid *comprising* a region encoding amino acids 222-223 of SEQ ID NO: 2, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, recognized divergent subject matter, and/or the need for non-coextensive literature search and/or separate sequence database searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Formal Matters

Applicant is reminded that the sequence identifier should be used when referring to a sequence in claims (for example, claim 2 does not refer to the SEQ ID NO.).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600